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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/849,746	09/05/97	LOHER U	LUDE14.313

IM31/1229

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EXAMINER	
GRAY,R	
ART UNIT	**PAPER NUMBER**
1732	

DATE MAILED: 12/29/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/849,746	Loher et al.
Examiner	**Group Art Unit**
Robin S. Gray	1732

☒ Responsive to communication(s) filed on *Oct 1, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-26* is/are pending in the application.

Of the above, claim(s) *17-26* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

1. **Applicants' election without traverse of Group I, claims 1-16, in Paper No. 8 is acknowledged. Accordingly, claims 17-26 are withdrawn from further consideration by the examiner, 37CFR 1.142(b) as being drawn to a non-elected invention.**

Oath/Declaration

2. **The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.**

The oath or declaration is defective because:

(1) The Declaration does not identify the "country" of citizenship of each inventor.

a. Each Applicants' citizenship is indicated as either "Swiss" or "German". However, the "country" of citizenship of each inventor should be indicated.

Claim Rejections - 35 USC § 112

3. **Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Regarding claim 1,

a. On line 1, --A-- should be inserted before "Process".

b. On line 2, "a short, long, and/or endless fiber is indefinite. It is unclear what length of fiber Applicants are claiming.

c. On line 4, "this" should be changed to --said--.

d. On lines 4-5, the words "the final form" lack literal antecedent basis.

e. On line 5, "the component" lacks literal antecedent basis.

f. On lines 6-7, The words "is first heated to" are indefinite in that the claim indicates that "the blank (7) is first pre-finished". What is the "first" step?

g. On line 7, --a-- should be inserted before "forming".

Regarding claim 2,

a. On line 1, --A-- should be inserted before "Process".

b. On lines 1-2, "are under tensile, bending, and/or torsion stress" is indefinite. It is unclear what length of fiber Applicants are claiming.

c. On line 5, "thermoplastic material" is indefinite. Is this the same as or different from the "thermoplastic material" previously recited?

d. On line 6, "this" should be changed to --said--.

e. On line 6, "the final form" lacks literal antecedent basis.

f. On lines 6-7, "the component" lacks literal antecedent basis.

g. On line 8, the words "is first heated to" are indefinite in that the claim indicates that "the blank (7) is first pre-finished". What is the "first" step?

h. On line 9, insert --a-- before "forming".

Regarding claims 3-16,

a. On line 1, --The-- should be inserted before "Process".

Regarding claim 3,

a. On lines 1-2, the words "the blank (7) is pre-finished" are indefinite in that claim 1 previously recites a "pre-finishing" step.

b. On lines 2-3, "the lengths" lacks literal antecedent basis.

c. On line 3, "the final component" lacks literal antecedent basis.

Regarding claim 4,

a. On line 1, the words "to 2" should be deleted.

b. On line 2, "endless fibers" are indefinite.

c. On lines 2-3, "the length of the blank" lacks literal antecedent basis.

d. On line 3, "the final component" lacks literal antecedent basis.

Regarding claim 5,

a. On line 2, "a blank" is indefinite. Is this the same as or different from the "thermoplastic material" previously recited?

b. On line 3, the antecedent of "its" is indefinite.

Regarding claim 6,

a. On line 2, "a blank" is indefinite. Is this the same as or different from the "thermoplastic material" previously recited?

b. On line 3, the phrase "for example (e.g.)" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 7,

a. On line 2, "the final component" lacks literal antecedent basis.

Regarding claim 8,

a. On lines 3 and 5, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 10,

a. On line 2, "a blank (7)" is indefinite. Is this the same as or different from the "the blank" previously recited?

b. On line 3, "is processed" is unclear. Processed in what respect?

Regarding claim 11,

a. On line 2, "the endless fibers" is indefinite as to wether endless fibers are used.

b. On lines 2-3, "the axis of the blank" lacks literal antecedent basis.

Regarding claim 12,

a. On line 2, "the fibers" lack literal antecedent basis.

Regarding claim 13,

a. On line 2, "the fibers" lack literal antecedent basis.

Regarding claim 14,

a. On line 2, "the fibers" lacks literal antecedent basis.

b. On lines 2-3, "the surface" lacks literal antecedent basis.

c. On line 3, --said-- should be inserted before "extrusion".

d. On line 2, it is unclear if "matrix material" s this the same as or different from the "thermoplastic material" previously recited?

Regarding claim 15,

a. On line 2, "the pressing temperature" and "the pressing speed" lack positive antecedent basis.

b. On line 3, "the position" lacks positive antecedent basis.

c. On line 3, "the alignment" lacks positive antecedent basis.

d. On lines 3-4, "the fibers" lacks literal antecedent basis.

e. On line 4, "the finished component" lacks literal antecedent basis.

Claim Rejections - 35 USC § 102

4. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:**

> **A person shall be entitled to a patent unless -- (b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 3-6, 11-12, 14, and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Devanathan (Patent Number: 4,978,360).**

Devanathan discloses a method for manufacturing composite implant prothesis (manufacturing components made of fiber-reinforced thermoplastic materials) having a core constructed from a plurality of carbon fibers. The method includes the steps of impregnating the strands of fiber (endless fibers having a length corresponding to at least the length of the blank for the final component) (endless fibers which run parallel to the axis of the blank) (a portion of the fibers have an orientation of 0 ° to 90 ° in the blank) with a polymer (blank); using a continuous process, such as pultrusion, to pull strands of fiber and polymer through several workstations; braiding an outer layer of polymer impregnated fiber over the core (a blank composed of layers of different fiber orientation in its length-wise direction); consolidating the outer layer with the core by application of heat and pressure; bending the core to a required geometry (the blank is brought into final form of the component in a negative mold by pressing into the negative mold by means of extrusion); applying an outer layer of polymer to obtain a final geometry for the composite implant prothesis. The core 16 is fed into a heated bath 18 filled with a polymer 19 (pre-treatment as rod material). The polymer impregnated tow is pulled through a pultrusion die 22 to provide a core 24 (the fibers are surrounded by matrix material, covering the surface, during extrusion). Carbon fiber 32 is braided over core 24 in two layers at a 45 degree angle. A second pultrusion die pulls the sheathed core through a series of reducing dies to melt the braided sheath into the polymer impregnated fiber core 24. Carbon fiber 30 impart torsional stability to the sheathed fiber core

24. After exiting pultrusion die 34 (the blank is first heated to a forming temperature), the sheathed core is placed in forming press 38 where heat and pressure are used to form or bend the sheathed core as desired (the blank is brought into final form of the component in a negative mold by pressing into the negative mold by means of extrusion, under pressure, in a hot-forming process). A second casing 56 is injection molding a suitable polymer thereto (this step also meets the step where the blank is brought into final form of the component in a negative mold under pressure in a hot-forming process forming an additional surface seal)(the blank is cut to a length required for the final product before the hot-forming process). Also, more than one polymer laminate is used in forming the blank. It is submitted that the formed article is under bending and tensile stress. See Figures; Abstract; column 1 through column 4.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

8. Claims 2, 7-10, and 15 are rejected under 35 U.S.C. § 103 as being unpatentable over Devanathan (Patent Number: 4,978,360).

The above discussion of Devanathan applies herein.

Specifically regarding claim 2, Devanathan does not disclose the blank is formed with a fiber proportion of more than a 50 volume-%.

However, the particular percentage of fiber making up the article is conventionally optimized through routine experimentation as a function of a variety of unclaimed parameters; such as: the intended function of the article, and the desired strength of the article. Further, it is well-known to increase or decrease the fiber volume or weight % based on the desired strength needed, and on the environment in which the article is to function.

Thus, it would have been obvious and well within ordinary skill in the art to have determined the optimum fiber proportion through routine experimentation in conjunction with the above identified parameters for the benefits received therefrom.

Specifically regarding claim 7, Devanathan does not disclose that the extrusion process is a push-pull extrusion process.

However, push-pull extrusion process are well-known in the art for orienting and strengthening fibers.

Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided push-pull process in the extrusion step of Devanathan for the purpose of strengthening and for providing orientation to the fibers for enhancing the strength of the final product.

Specifically regarding claim 8, while Devanathan discloses that the blank is heated, a temperature is not specified.

However, the particular temperature to which the blank is heated during the extrusion process is a function of the particular material used in the process; and it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided the claimed temperatures in the method of Devanathan where the polymer material and the materials used by Devanathan are the same materials.

Specifically regarding claim 9, Devanathan does not disclose using a release agent during the hot-forming process.

However, release agents, such as carbon or graphite, are well-known and conventionally used in the art; and, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided release agents in the hot-forming method of Devanathan for the benefit of providing easy release of the formed article form the mold and to avoid sticking between the mold and the materials used.

Specifically regarding claim 10, Devanathan does not disclose using polyaryl ether ketones for the fiber material.

However, the particular materials used is a function of a variety of unclaimed parameters; such: the cost and availability of the material or fibers, the strength of the fiber or material based on the intended function of the article, how much of the material or fiber material will be needed to meet the strength requirement or the volume % requirement, and the operating and forming temperature of the fiber or material.

Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided polyaryl ether ketones for the fiber material based on the above identified parameters for the benefits received therefrom.

Specifically regarding claim 15, Devanathan does not disclose that the pressing temperature and the pressing speed are variables in the process to change position and alignment of the fibers.

However, pressing temperature and speed are conventional variables in molding processes which are routinely adjusted for the purpose of positioning and alignment of fibers based on the type of resins and fibers used.

Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have optimized routine variables in the method of Devanathan, such as pressing speed and temperature, to allow for positioning and alignment of the fibers based on the types of fibers and resin materials used.

Prior Art of Record

9. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure. The prior art references listed on the attached PTO 892, not used in the prior art rejections, all teach the general state of the art.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Gray whose telephone number is (703) 305-7251. The best time to reach the examiner is on Monday-Friday from 8:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Jan H. Silbaugh, can be reached at (703) 308-3829. The fax number for group 1730 is (703) 305-7718. When filing a fax in Group 1730, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and use fax number (703) 305-7718. For "Official After Final Faxes", please use fax number (703) 305-3599. For "unofficial" draft documents and other communication with the PTO that are not for entry into the file of the application, use fax number (703) 305-7115. This will expedite processing of papers.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Robin S. Gray

December 15, 1998

JAN H. SILBAUGH
SUPERVISORY PATENT EXAMINER
ART UNIT 1732

12/18/98